# *Biosecurity Risk Assessment*

**SNL Biosecurity Team**

**Chemical & Biological Weapons Nonproliferation**

**International Security Center**

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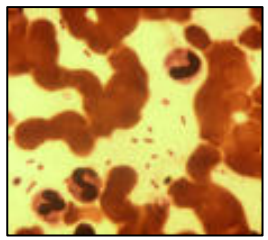
# Biosecurity Based on Risk Management

- **Biosecurity risk management considerations**
  - Critical not to unduly compromise legitimate bioscience operations
  - Most biological materials can be isolated from nature
  - A security system cannot protect every asset against every conceivable threat
  - Security resources are not infinite
  - Security systems should be based on the asset or material that requires protection
  - Security systems should be designed to address unique situations
  - Impact operations only to the level required Use limited resources efficiently


# Challenges to Securing Biological Agents

- **Dual-use characteristics**
  - Valuable for legitimate, defensive, and peaceful commercial, medical, and research applications
    - Possession does not imply intent
- **Nature of the material**
  - Living and self-replicating organisms
  - Cannot be reliably quantified
    - Cannot keep an accurate inventory
  - Used in very small quantities
    - Cannot visually discern whether material is missing
  - Exist in many different process streams in facilities
    - Decentralization makes restricting access to authorized individuals more difficult
  - Contained biological samples are virtually undetectable
    - Cannot use sensors to alert unauthorized removal
- **Laboratory culture**
  - Biological research communities not accustomed to operating in a security conscious environment



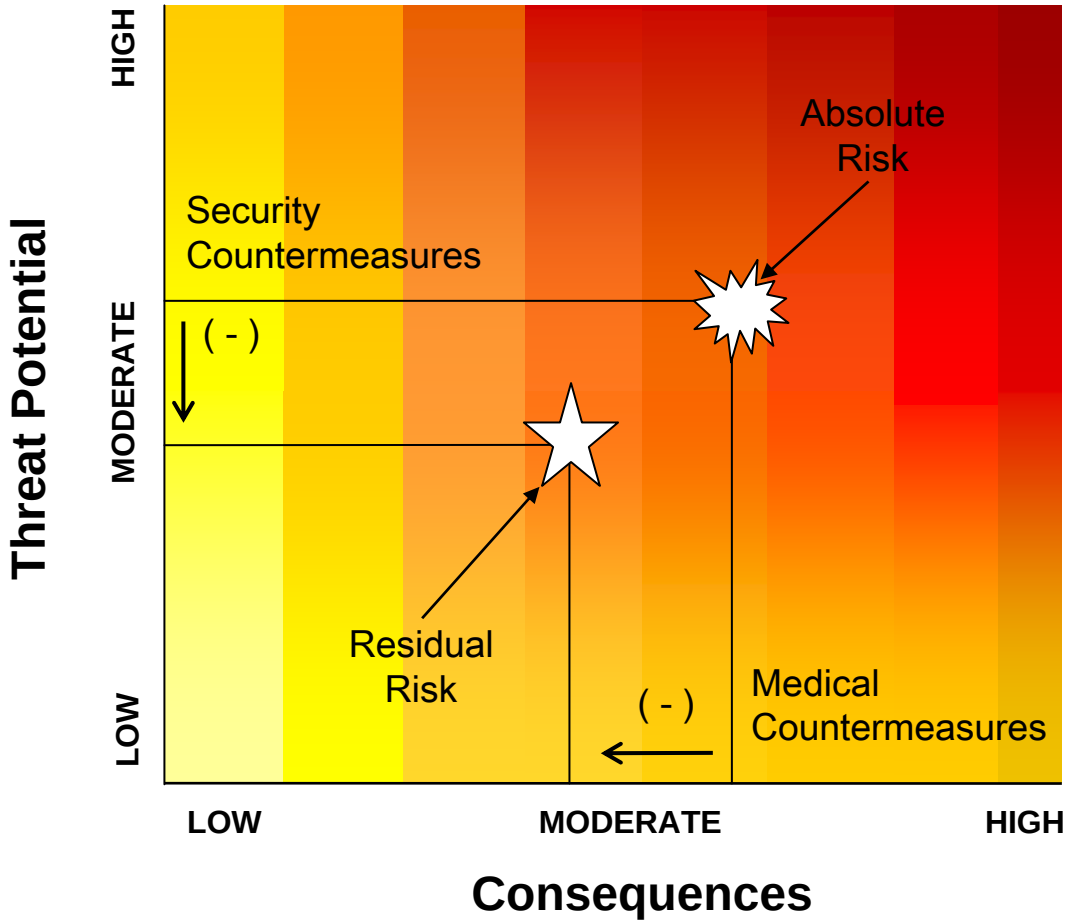
*Yersinia pestis*

# Biosecurity Cost-Benefit Considerations

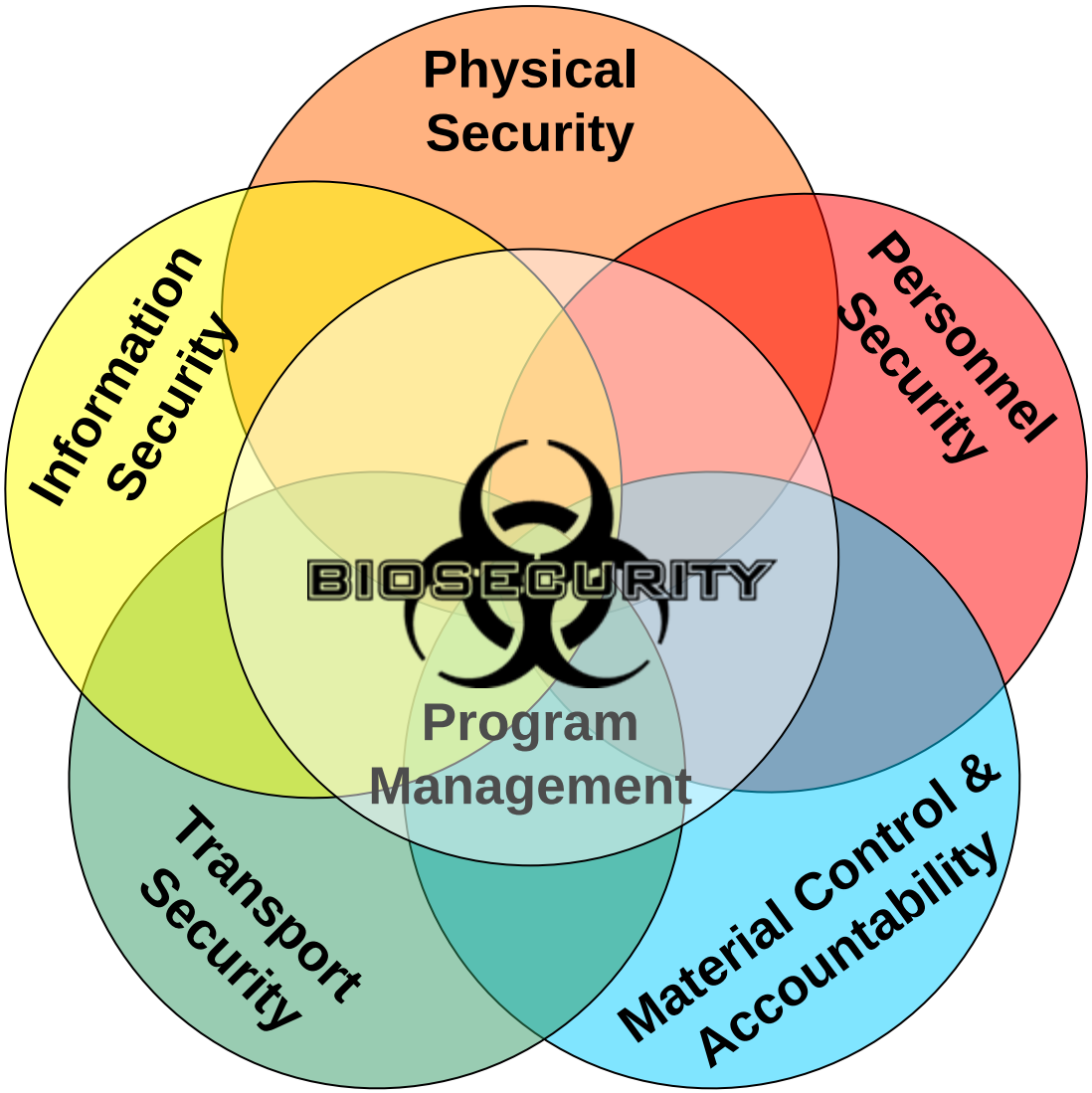
- Bioscience facilities are not unique repositories
  - Most agents can be isolated from nature
  - Many similar collections of agents exist worldwide
- Relatively few agents can be easily grown, processed, weaponized, and successfully deployed while maintaining virulence/toxicity
  - Very few agents used as a weapon could cause mass human, animal, or plant casualties
- Need a methodology to make informed decisions about how to design an effective and efficient biosecurity system

*FMD outbreak, U.K.*

# Biosecurity Risk Assessment and Mitigation



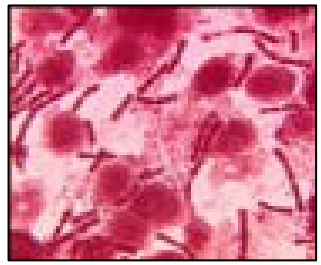
# Components of Biosecurity



# Risk Management

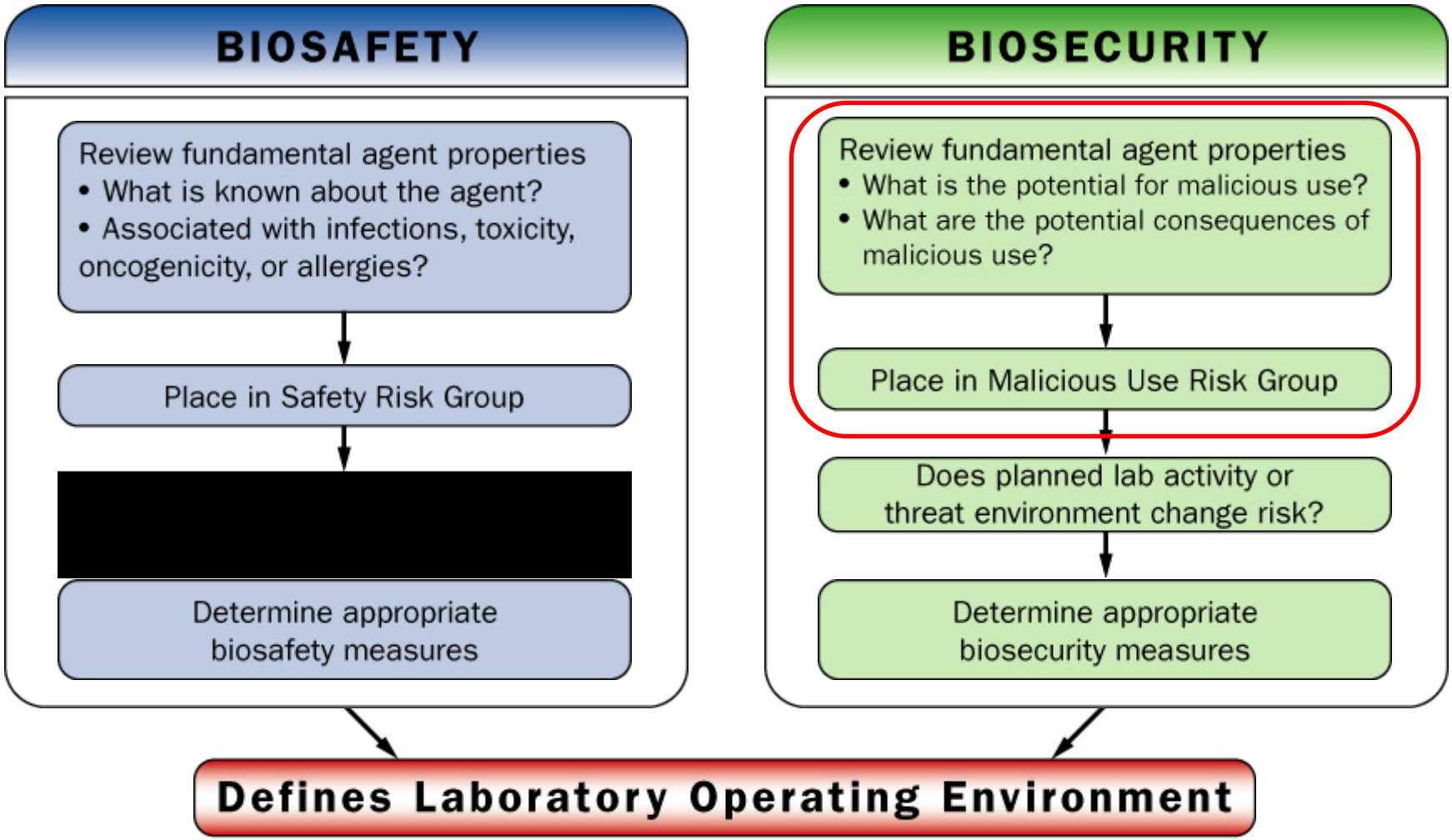
- **Establishes which assets should be protected against which threats**
  - **Assets include items that are:**
    - **Dangerous**
    - **Hard to replace**
    - **Rare**
    - **Critical to operations**
- **Ensures that the amount of protection provided to a specific asset, and the cost for that protection, is proportional to the risk of the theft or destruction of that asset**
- **Begins with a risk assessment**
- **Proceeds with risk mitigation**
- **Continuously improves with monitoring and adjustment**

# Biosecurity Risk Assessment



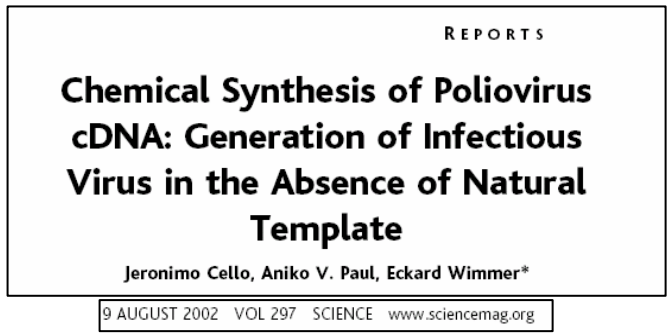
1. Evaluate assets (agent assessment)
2. Evaluate threat (lab activity and threat environment)
3. Evaluate risk

# Integrated Biosafety and Biosecurity



# Malicious Use Risk Group Evaluation

- **Assess value of the agents from an adversary's perspective**
  - **Consequences**
    - **Transmissibility**
    - **Medical effects (morbidity and mortality)**
    - **Psychological impact**
    - **Economic impact**
  - **Weaponization potential**
    - **Acquisition**
    - **Production**
      - **Ease of growth**
      - **Ease of processing**
      - **Ease of storage**
    - **Dissemination**
      - **Modes (e.g. Aerosol, Oral)**
      - **Environmental hardiness**

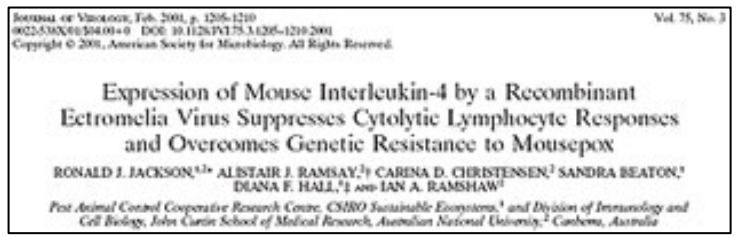


REPORTS

Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template

Jeronimo Cello, Aniko V. Paul, Eckard Wimmer*

9 AUGUST 2002 VOL 297 SCIENCE www.sciencemag.org



Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox

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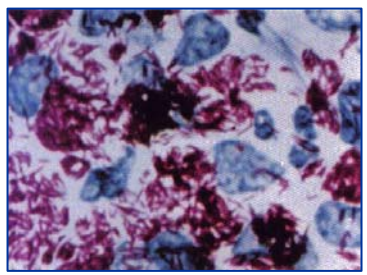
# Malicious Use Risk Groups

- **Nonpathogenic**
  - Malicious use would have insignificant or no consequences
- **Low Malicious Use Risk (LMUR)**
  - Difficult to deploy, and/or
  - Malicious use would have few consequences
- **Moderate Malicious Use Risk (MMUR)**
  - Relatively difficult to deploy, and
  - Malicious use would have localized consequences with low to moderate casualties and/or economic damage
- **High Malicious Use Risk (HMUR)**
  - Not particularly difficult to deploy, and
  - Malicious use could have national or international consequences, causing moderate to high casualties and/or economic damage
- **Extreme Malicious Use Risk (EMUR)**
  - Would normally be classified as HMUR, except that they are not found in nature (eradicated)
  - Could include genetically engineered agents, if they were suspected of being a HMUR

# LMUR Agent Example: *Mycobacterium leprae*

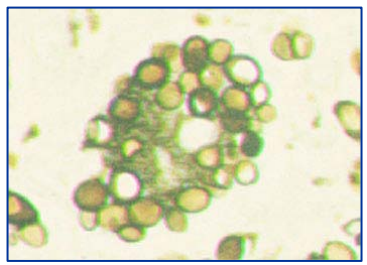
- **Consequences**
  - **Leprosy**
    - **Not highly virulent, most exposed people do not develop leprosy**
    - **Not highly contagious**
    - **Completely curable – majority recover without treatment**
- **Weaponization potential**
  - **Production is a significant challenge**
  - **Not environmentally hardy**
- **Assessment: low consequences and low weaponization potential**



***Mycobacterium leprae***

# MMUR Agent Example: *Coccidioides immitis*

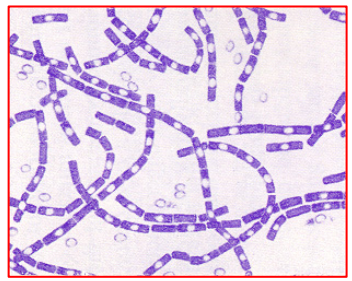
- **Consequences**
  - **Coccidioidomycosis (Valley fever)**
    - **Usually asymptomatic, 30-40% of infected become ill**
    - **Not contagious**
    - **5-10 out of every 1000 infected develop life-threatening infection**
- **Weaponization potential**
  - **Requires technical skills to handle**
  - **Easy to procure virulent strain (wide endemic area)**
  - **Easy to grow colonies and produce spores**
- **Assessment: low to moderate consequences and moderate weaponization potential**



***Coccidioides immitis***

# HMUR Agent Example: *Bacillus anthracis*

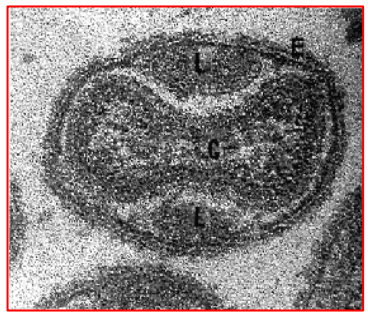
- **Consequences**
  - **Pulmonary anthrax (via aerosolized anthrax)**
    - **High fatality rate**
    - **Not contagious, relatively high infectious dose required**
    - **Early diagnosis is difficult**
- **Weaponization potential**
  - **History of weaponization and terrorist use**
  - **Wide endemic area but many less virulent strains**
  - **Easy to grow colonies and produce spores**
  - **Very stable in environment and storage**
- **Assessment: moderate to high consequences and relatively high weaponization potential**



***Bacillus anthracis***

# EMUR Agent Example: Variola major virus

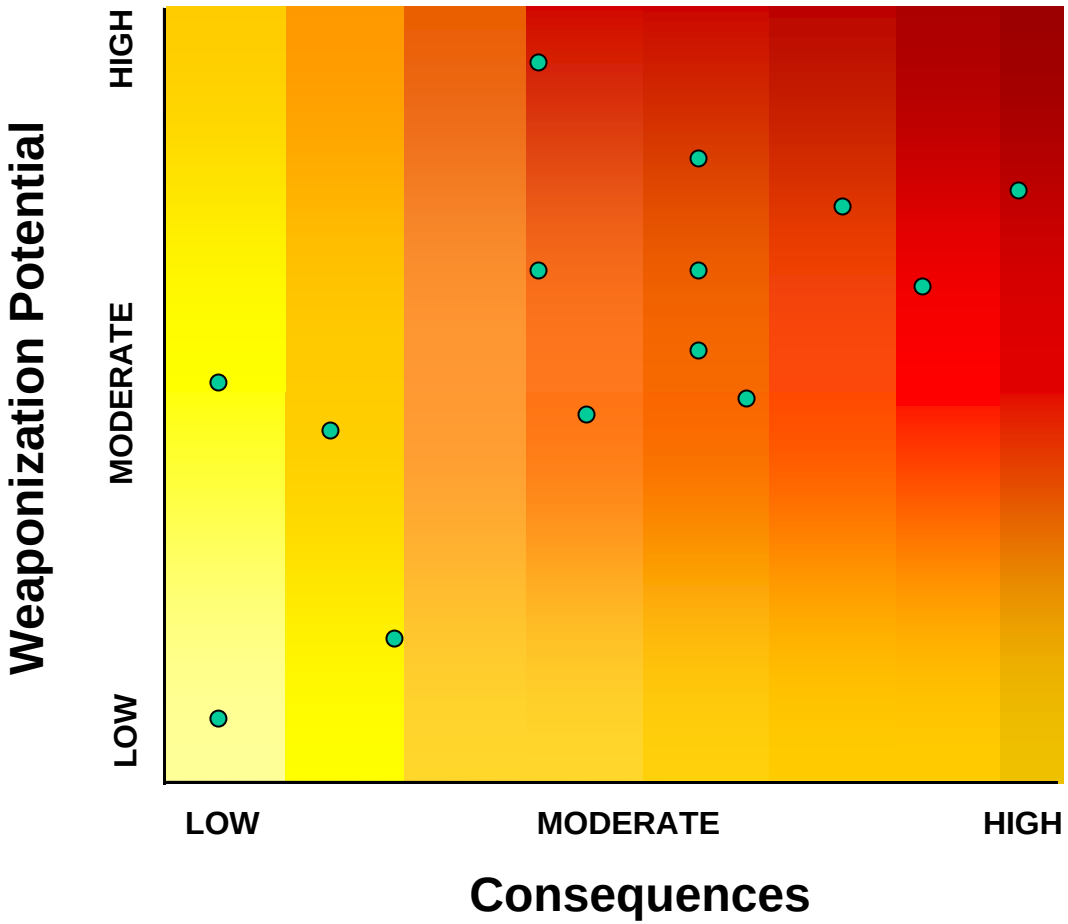
- Consequences
  - Smallpox
    - High fatality rate
    - Contagious
    - Very few people vaccinated
- Weaponization potential
  - History of weaponization
  - Very stable in aerosol
  - Extremely difficult to obtain
- Assessment: high consequences and moderate weaponization potential



*Variola major*

Patient's leg covered in smallpox

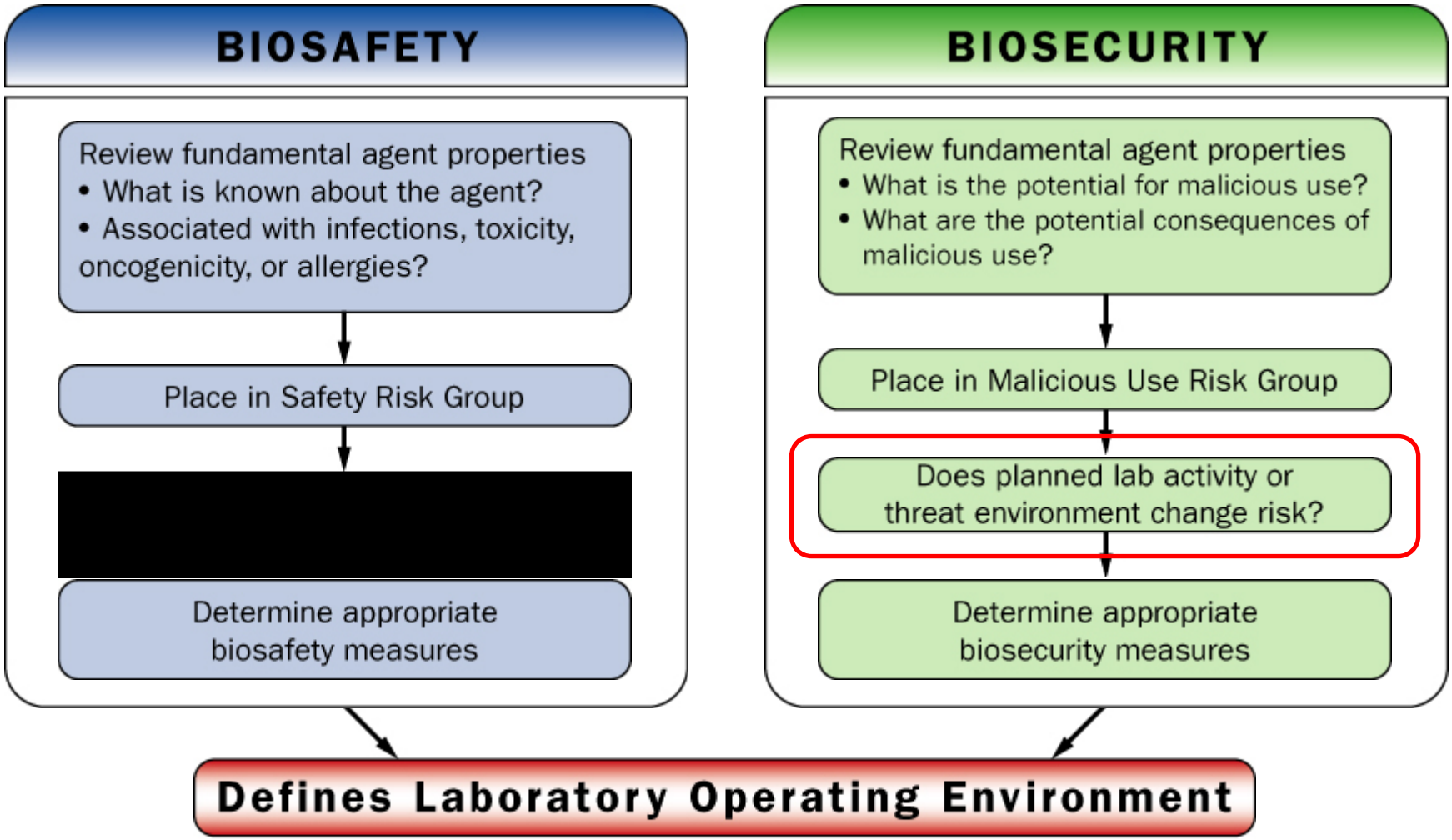
# Results of Malicious Use Risk Group Evaluation



# Other Assets at Biological Facilities

- **Security Information or Systems**
  - **May be targeted to facilitate gaining access to dangerous biological materials**
- **Other Facility Assets**
  - **May be targeted by political extremists, disgruntled employees, etc.**
  - **May include:**
    - **High containment laboratories**
    - **Animals**

# Integrated Biosafety and Biosecurity



# Elements That May Modify Risk

- **Consider lab experiment**
  - **Does planned experiment produce an agent with higher weaponization potential or higher potential consequences?**
    - **For example: Increased stability, GMOs, large quantities, aerosol challenges**

# Threat Environment

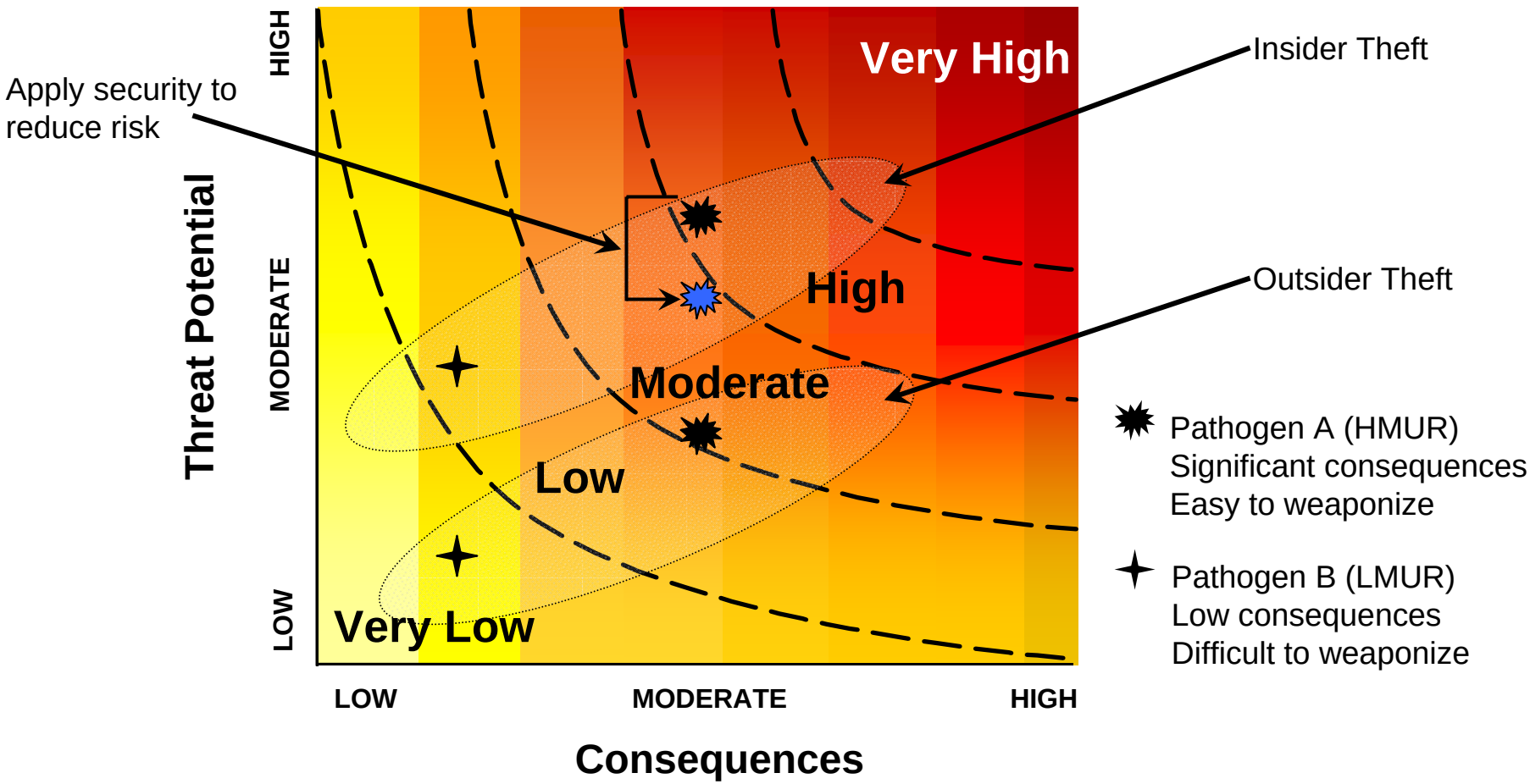
- **Adversary Classes**
  - Terrorist
  - Extremist
  - Criminal
- **Insiders**
  - Authorized access to the facility, dangerous pathogens, and/or restricted information
  - Distinguish Insiders by level of authorized access
    - Site
    - Building
    - Asset
  - Facility management, site security, and local law enforcement interviews
- **Outsiders**
  - No authorized access
  - Local law enforcement, site security, and intelligence community interviews

# Threat Potential

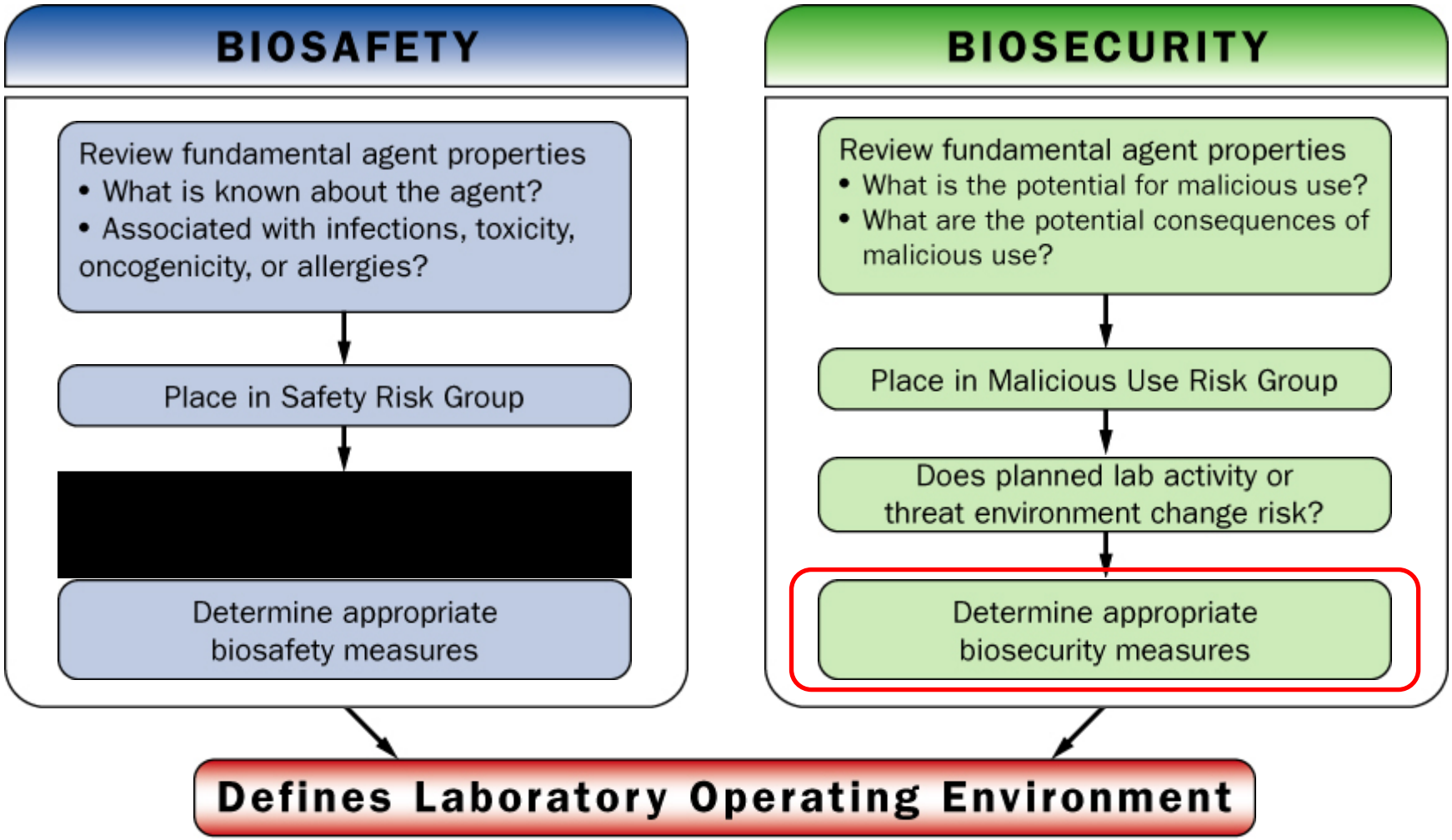
**Evaluate threat potential of possible adversaries:**

- **Motive**
  - **Asset Attractiveness**
    - **How well does the acquisition or sabotage of the asset achieve the adversary's objective, or lead to achieving the adversary's objective?**
- **Means**
  - **Capability**
    - **Does the adversary have the skills, knowledge, and tools necessary to conduct the attack/meet the objective?**
- **Opportunity**
  - **Access**
    - **Does the adversary have routine access?**
    - **Are there other authorized individuals that might be present?**

# Biosecurity Risk: Insider vs. Outsider Threat



# Integrated Biosafety and Biosecurity



# Conclusions

- Need to integrate biosafety and biosecurity considerations into decisions about laboratory operations
- Biological facility risk assessment provides an opportunity to concentrate resources on the highest risks
  - Tiered system of protection based on risk assessment and risk management methodologies
- Parallels exist between safety and security risk assessment processes